NDA 19-700/S-014

Allergan, Inc.
Attention: Elizabeth Bancroft
Senior Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92713-9534

27 APR 2001

Dear Ms. Bancroft:

Please refer to your supplemental new drug application dated December 21, 1998, received December 22, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Acular (ketorolac tromethamine ophthalmic solution) 0.5%.

We acknowledge receipt of your submissions dated July 21, 1999; May 25 and August 4, 2000; and February 9 and March 21, 2001. Your submission of May 25, 2000, constituted a complete response to our July 13, 1999, action letter.

This supplemental application provides for revised labeling of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

This approval affects only the changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected. Based on adverse reaction reports submitted, the Warnings, Precautions and Adverse Reactions sections of all ophthalmic NSAIDs are currently under review. Should additional information relating to the safety and effectiveness of these drugs become available, labeling revisions may be required.

The final printed labeling (FPL) must be identical to the attached copy of the draft labeling of the package insert submitted February 9, 2001.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-700/S-014." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Raphael R. Rodriguez, MSA, Project Manager, at (301) 827-2090.

Sincerely,

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research